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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/428,458	10/28/1999	KJETIL TASKEN	Q-56244	4681

7590 06/29/2005

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EXAMINER	
BOWMAN, AMY HUDSON	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/428,458	TASKEN ET AL.	
	Examiner	Art Unit	
	Amy H. Bowman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40,45,48 and 49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40,45,48 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 2/9/2005 has been considered. The rejections from the previous office action mailed 1/3/2005 are hereby withdrawn. The following rejections and/or objections are newly applied.

With entry of the amendment filed on 4/4/2005, claims 40, 45, 48 and 49 are pending in the application. Applicant has canceled claims 1-39, 41-44, 46, 47, 50 and 51.

New Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 40 is rejected under 35 U.S.C. 102(b) as being anticipated by Ogreid et al. Ogreid et al. teach Rp-piperidino-cAMPS in a solution and that piperidino and exocyclic sulfur substitutions generate cAMP analogs that completely discriminate between site A and B of cAMP-dependent protein kinases (see page 1090, 1st paragraph, 2nd column). Therefore, the invention of claim 40 is anticipated by Ogreid et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 45, 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gjertsen, in view of Hofmann et al. and Jastorff et al. (WO 93/21929).

The invention of the above claims is drawn to a method for enhancing T cell proliferation in a subject in need thereof, comprising administering to said subject a pharmaceutical composition comprising a pharmaceutically effective amount of a Rp-8-substituted cAMP (i.e. Rp-8-Br-cAMPs, Rp-8-Cl-cAMPs, or Rp-8-(4-chlorophenyl-thio)-cAMPs) and a pharmaceutically acceptable adjuvant or filler.

Gjertsen et al. teach a method of inhibiting cAMP with cAMP antagonists (Rp-cAMPS analogs) in cell culture. Gjertsen et al. specifically teach Rp-8-Br-cAMPs, Rp-8-Cl-cAMPs and Rp-8-(4-chlorophenyl-thio)-cAMPs. Gjertsen et al. teach a composition comprising the cAMPS and a buffer (see page 20600, col. 1), wherein the buffer would be encompassed in the term "a pharmaceutically acceptable adjuvant or filler". Additionally, Gjertsen et al. teach that inhibition of cAMP results in enhanced DNA replication.

Gjertsen et al. do not teach a method of administering a cAMP antagonist to a subject in need thereof.

Hofmann et al. teach restoration of T-cell function in HIV infection by reduction of intracellular cAMP levels with adenosine analogues. Hofmann et al. examined cAMP

levels in men who had been HIV-seropositive for 5 or more years, whom are considered subjects in need of treatment. Hofmann et al. teach that restoration of normal T-cell functions should be of great benefit in the treatment of HIV infection.

Jastorff et al. teach Rp-8-Cl-cAMPS and pharmaceutical compositions comprising the compound (see pages 12 and 13 and claims 18-22). Jastorff et al. teach a chemotherapeutic method comprising administering Rp-8-Cl-cAMPs to a mammal (see claim 27). Jastorff et al. teach the effect of 8-Cl-cAMP on *in vivo* tumor growth and that Rp-8-Cl-cAMPs has a similar mechanism of action as 8-Cl-cAMP (see page 55). Jastorff et al. teach that Rp-8-Cl-cAMPs are a better candidate for chemotherapy, because they are more resistant to hydrolysis.

It would have been obvious to perform the method of inhibiting cAMP with cAMP antagonists as taught by Gjertsen et al. to restore T-cell function because Hofmann et al. teach that reducing cAMP levels restores T-cell function, which is crucial because HIV-seropositive individuals without AIDS showed significant increases in intracellular cAMP levels. It would have further been obvious because Gjertsen et al. teach that inhibition of cAMP results in enhanced DNA replication, which would result in an increased T-cell population. It would have been obvious to use Rp-8-Br-cAMPs, Rp-8-Cl-cAMPs, or Rp-8-(4-chlorophenyl-thio)-cAMPs, because each were known in the art to be cAMP antagonists at the time the invention was made and Jastorff et al. teaches that Rp analogs are more resistant to hydrolysis, rendering them better candidates for chemotherapeutic agents. One would be motivated to practice the method of Gjertsen et al. in a subject in need thereof because Hofmann et al. teach that drugs that

decrease intracellular cAMP levels may be beneficial in the treatment of AIDS and Jastorff et al. teach administration of such compounds *in vivo*. Finally, one would have had a reasonable expectation of success to administer such compounds to a subject in need thereof because Jastorff et al. teach methods of treating mammals by administering cAMP antagonists *in vivo*.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is 571-272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service

center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Amy H. Bowman
Examiner
Art Unit 1635

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